

JAN 20 2012

Section 6**510(k) Summary**

APPLICANT: Interventional Spine, Inc.

DATE PREPARED: November 27, 2011

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TRADE NAME: Opticage™ Interbody Fusion Device

COMMON NAME: Spinal Implant

CLASSIFICATION NAME: Intervertebral Body Fusion Device

DEVICE CLASSIFICATION: Class II

REGULATION NUMBER 888.3080 (product code: MAX)

PREDICATE DEVICES: L-Varlock Lumbar Cage (K080537)
Caliber Spacer (K102293)

Substantially Equivalent To

The Opticage Interbody Fusion Device is substantially equivalent in intended use, principal of operation and technological characteristics to the L-Varlock Lumbar Cage (K080537) and the Caliber Spacer (K102293).

Description of the Device Subject to Premarket Notification

The Opticage Interbody Fusion Device is a lumbar intervertebral body fusion device manufactured from implant grade titanium alloy. The Opticage Interbody Fusion Device consists of an upper and lower titanium plate and two titanium wedges that interact to change the height of the device. The device is available in a single configuration that ranges in length from 29mm (closed) to 21mm (expanded) and ranges in nominal height from 9mm (closed) to 14mm (expanded). The top and bottom of the device are fenestrated and contain openings to enhance bony in growth. The Opticage Interbody Fusion Device is provided non-sterile, for single use only.

Indication for Use

The Opticage Interbody Fusion Device is a posterior lumbar intervertebral body fusion device and is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. These DDD patients

Section 6**510(k) Summary**

may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The Opticage Interbody Fusion Device can be implanted via posterior or transforaminal approach.

DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Candidates for surgery should be skeletally mature and have had a six month course of conservative treatment. These patients may have had primary or secondary surgery, but no previous fusion at the involved levels.

The device is not intended to be used as a stand-alone device. It must be used with supplemental internal spinal fixation systems that have been cleared for use in the lumbar spine (i.e. facet screw fixation systems, facet compression devices and posterior pedicle screw and rod systems).

Technical Characteristics

The Opticage Interbody Fusion device and the referenced predicates are all intended for use as intervertebral body fusion devices. The Opticage Interbody Fusion Device and the predicates are fabricated from well-known osteo-compatible materials with a long history of biocompatibility. The Opticage Interbody Fusion Device and the predicates are used as implantable spacers to provide structural support and maintain height between the adjacent vertebrae. All devices are designed to be used in conjunction with autogenous bone graft. All devices require the use of commercially available supplemental internal spinal fixation systems. All devices share the same geometry, rectangular box shaped with openings and toothed surface on the top and bottom. All devices are expanded by means of a rotational thread (screw) after insertion.

Performance Data

All necessary performance testing, has been completed for the Opticage Interbody Fusion Device including those identified in ASTM F2077 (static and dynamic compression, static compression shear, static and torsional loading paradigms), subsidence per ASTM F2267, expulsion, and evaluation of wear debris/particulates to assure substantial equivalence to the predicate devices.

Basis for Determination of Substantial Equivalence

Upon reviewing the performance data provided in this submission and comparing intended use, design, materials, principle of operation and overall technological characteristics, the Opticage Interbody Fusion Device is determined by Interventional Spine, Inc., to be substantially equivalent to existing legally marketed devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Interventional Spine, Incorporated

% Ms. Jane Metcalf

Vice President of Quality Assurance, Regulatory and Clinical Affairs
13700 Alton Parkway, Suite 160
Irvine, California 92618

JAN 20 2012

Re: K113527

Trade/Device Name: Opticage Interbody Fusion Device

Regulation Number: 21 CFR 888.3080

Regulation Name: Intervertebral body fusion device

Regulatory Class: Class II

Product Code: MAX

Dated: November 27, 2011

Received: November 30, 2011

Dear Ms. Metcalf:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

Page 2 – Ms. Jane Metcalf

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

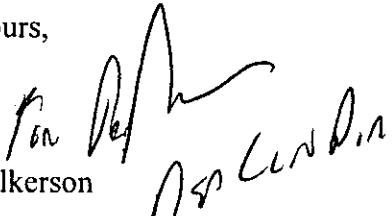
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K113527

Device Name: **Opticage™ Interbody Fusion Device**

Indications for Use:

The Opticage Interbody Fusion Device is a posterior lumbar intervertebral body fusion device and is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The Opticage Interbody Fusion Device can be implanted via posterior or transforaminal approach.

DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Candidates for surgery should be skeletally mature and have had six months of conservative treatment. These patients may have had primary or secondary surgery, but no previous fusion at the involved levels.

The device is not intended to be used as a stand-alone device. It must be used with supplemental internal spinal fixation systems that have been cleared for use in the lumbar spine (i.e. facet screw fixation systems, facet compression devices and posterior pedicle screw and rod systems).

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113527